



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 27 2004

Food and Drug Administration
Rockville MD 20857

Steven G. Wigrizer, Esq.
Wapner, Newman, Wigrizer, & Brecher
115 South 21st Street
Philadelphia, PA 19103-4483

Re: Docket No. 2004P-0220/CP1

Dear Mr. Wigrizer:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on May 7, 2004, and amended on May 17, 2004. Your petition requests that the Agency determine whether Zithromax (azithromycin) 250-mg oral capsules were withdrawn from sale for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0220

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